



To: Messrs. Howson and Howson

Application No.93105371

**English translation of**  
**NOTIFICATION FOR THE OPINION OF EXAMINATION**

**Addressee:** Wyeth

**Attorney:** Mr. Ted Ho

**Date of official letter:** December 11, 2007 (received on December 13, 2007)

**Official Letter No.:** 2(5)01087/09620687030

**Subject:**

Concerning the patent application No. 93105371 after examination, it is considered that something unclear and indefinite still exists as indicated in the **Explanation I**. Please have the respondent explanation or amendments submitted in duplicate to this Office within sixty (60) days after receiving this notice. If no respondent data are presented within the prescribed period, then the decision will be made according to the original contents.

**Explanation:**

**I. After examination, the present application is deemed as:**

1. The present invention entitled "ANTINEOPLASTIC COMBINATIONS" has 65 claims in total, in which Claims 1, 25, 30, 31, 32, 38, 39, 44, 45, 51, 52, 55, 56, 59, 62, and 65 are independent claims and the others are dependent claims.
2. The subject matter of Claims 1-29 and 31-38 are method for treating diseases and such subject matters do not comply with the provision of Item 2, Paragraph 1 of Article 24 of the Patent Law.



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3. Documents Clinical Cancer Research Vol. 9, 524s-532s, Jan 2003 and WO 02/066019 (2002/08/29) have disclosed the combination of two medicaments of Claim 30 used in the treatment of breast cancer. Further, WO 02/40000 (2002/05/23) has disclosed using CCI-779 for treating various tumors. Accordingly, the "composition" of Claims 30 and 62-64, the "use" of Claims 39-51 and 55-58, the "product" of Claims 52-54, and the "pharmaceutical pack" of Claims 59-61 can be accomplished by those of ordinary skill in the art based on the prior arts. The present invention therefore has no inventive step and does not comply with the provision of Paragraph 4 of Article 22 of the Patent Law.

4. Claims 31, 38, 44, 51, and 65 relate to a combination of 42-O-(2-hydroxy)ethyl rapamycin and an aromatase inhibitor; however, no data showing synergic effects of the combination are provided in the specification. These claims do not comply with the provision of Paragraph 2 of Article 26 of the Patent Law. In addition, no data can support that the combination is useful in treating any type of tumors. These claims will not comply with the provision of Paragraph 3 of Article 26 of the Patent Law even if the subject matter is amended.

**II.** In accordance with the provisions of Rule 28 of the Implementing Regulations of the Patent Law, if there are supplements, amendments to the specification or drawings, an application for supplements and amendments in duplicate shall be submitted. Therefore, the specification on which the portions of supplement or amendment are underlined, or the corrected pages of the drawings in duplicate shall be submitted, and the specification without underlines after supplement or amendment, or the replacement pages of the drawings in triplicate shall be submitted. If the page numbers of the original specification or drawings are not continuous because of such supplement or amendment, a complete set of specification or drawings in triplicate after supplement or amendment shall be submitted to this Office.

**III.** If the applicant intends to demonstrate or explain in this Office, he or she shall mark "interview is requested" in the Response. If this Office deems it necessary, the place and time of the "interview" will be further arranged and an Official fee of **NT\$1,000.00** should be paid at the same time.



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**IV. Enclosed please find a copy of search report in English and three citations shown in the Attachment 1.**